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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,072	03/22/2004	Mingqi Lu	20335-00165	1395

28534 7590 06/27/2007

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,072	LU ET AL.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 5/23/2007. Claims 1-15, 17 have been withdrawn, claims 22-25, 30, 37-40 have been amended, claims 44-48 have been added new and claims 16, 18-21 has been canceled. Applicants' election of group II, claims 22-43 in the reply filed on 5/23/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus the restriction requirement elected is made final. Claims 22-48 are currently pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22, 24, 26-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Mo et al. (US 2004/0131664, effective filing date Jan 3 2003).

Mo et al. teaches a composition comprising prostaglandin E (PGE compounds), a topical anesthetic such as dyclonine, lidocaine etc (about 0.01 to 4 %) (p 6, para 0064), a polymeric thickener such as a modified guar gum (p 4, para 0042), a lipophilic component such as ethanol and ethyl laurate (p 6, para 0067), water (p 6, para 0067) and a buffer system (p 5, para 0053). The reference teaches the composition comprising glyceryl ester such as triolean (p 5, para 0051), emulsifiers such as sucrose stearate, trimyristin (p 4, para 0050, p 5, para 0051), up to about 5 percent fragrance such as myrtenol (p 6, para 0064), and a preservative such as methyl paraben (p 6, para 0066) in the treatment of male and sexual dysfunctions in human patients e.g. impotence, premature ejaculation etc. The reference teaches the treatment of premature ejaculation but does not explicitly teach the prolongation of ejaculation latency in the patient. It is inherent that administering the same composition as claimed in claim 23 would confer prolongation of ejaculation latency to the patient by treating the premature ejaculation disorder. Also, it is inherent that administering the same composition as claimed the functionality and the properties will be same and hence the ejaculation latency time will be no less than two minutes or will be greater than two minutes and will be prolonged by at least two minutes as claimed in claims 44-46.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mo et al. (US 2004/0131664, effective filing date Jan 3 2003) in view of Sallis (US 2003/0144318) and further in view of Samour et al. (U.S. 5, 942, 545).

Mo et al. teachings discussed as above.

The reference does not teach the amount of prostaglandin in the composition in a method of treating premature ejaculation.

Sallis et al. teaches that sexual dysfunction can include erectile dysfunction (ED) and premature ejaculation (PE) (p 3, para 0033) and a vasodilator such as prostaglandin E (3-12 ug/ml) can be used (para 0035) in the treatment of such disorders.

The reference does not specifically teach the amount of prostaglandin to be 0.1 – 0.5 mg as claimed in claims 23 and 25 of the instant application.

Samour et al. teaches an amount of about 25 ug to 4 mg prostaglandin E in a composition for the treatment of erectile dysfunctions (see Abstract, col. 6, lines 66-67).

It would have been obvious to one of ordinary skill in the art to employ an amount of 0.1-0.5 mg of prostaglandin in a method of treatment of premature ejaculation because of the teachings of Sallis and Samour. Sallis teach that premature ejaculation and erectile dysfunction are sexual dysfunctions and further teach the use of prostaglandin. Samour teaches an amount of 25 ug to 4 mg prostaglandin E for the treatment of erectile dysfunctions and hence one of ordinary skill in the art would have been motivated to administer such an amount of prostaglandin E to treat premature ejaculation as it is another sexual dysfunction in the expectation of attaining similar therapeutic benefits and safety. .

Claims 22-43, 47, 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US 2003/0220292) in view of Sallis (US 2003/0144318) and further in view of Samour et al. (U.S. 5, 942, 545).

Okada et al. teaches a method of treating erectile dysfunction comprising prostaglandin E (PGE compounds) (see Abstract), a topical anesthetic such as dyclonine, lidocaine etc (about 0.01 to 4 %) (para 0105), a polymeric thickener such as a modified guar gum (para 0079), a lipophilic component such as ethanol and ethyl laurate (para 0055), water (para 0097) and a buffer system (para 0022). The reference teaches the composition comprising glyceryl ester such as triolean (para 0094), emulsifiers such as sucrose stearate, trimyristin (para 0093, 0094), up to about 5 percent fragrance such as myrtenol (para 0105), and a preservative such as methyl paraben (para 0025, 0098). The reference further teaches the administration of the

composition comprising prostaglandin, anesthetic, thickener, 5-30 minutes, before sexual intercourse (para 0109).

The reference does not teach a method of treating premature ejaculation comprising a composition as claimed in claim 22 of the instant application.

Sallis et al. teaches that sexual dysfunction can include erectile dysfunction (ED) and premature ejaculation (PE) (p 3, para 0033) and a vasodilator such as prostaglandin E (3-12 ug/ml) can be used (para 0035) in the treatment of such disorders.

It would have been obvious to one of ordinary skill in the art to treat a method of premature ejaculation a composition as claimed in claim 22 of the instant application because of Sallis et al.'s teachings. The reference teaches that sexual dysfunction can include erectile dysfunction (ED) and premature ejaculation. Hence one of ordinary skill in the art would have been motivated to apply the same composition that had been taught by Okada et al. for the treatment of erectile dysfunction to treat another sexual dysfunction such as premature ejaculation in expectation of similar therapeutic efficacy and benefits and administration of the same composition as claimed in claim 23 in the treatment of premature ejaculation would inherently confer prolongation of ejaculation latency in the patient.

Sallis et al. does not specifically teach the amount of prostaglandin to be 0.1–0.5 mg as claimed in claims 23 and 25 of the instant application.

Samour et al. teaches an amount of about 25 ug to 4 mg prostaglandin E in a composition for the treatment of erectile dysfunctions (see Abstract, col. 6, lines 66-67).

It would have been obvious to one of ordinary skill in the art to employ an amount of 0.1-0.5 mg of prostaglandin in a method of treatment of premature ejaculation because of the teachings of Sallis and Samour. Sallis teach that premature ejaculation and erectile dysfunction are sexual dysfunctions and further teach the use of prostaglandin. Samour teaches an amount of 25 ug to 4 mg prostaglandin E for the treatment of erectile dysfunctions and hence one of ordinary skill in the art would have been motivated to administer such an amount of prostaglandin E to treat premature ejaculation as it is another sexual dysfunction in the expectation of attaining similar therapeutic benefits and safety.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER